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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/784,807

02/24/2004

Mark Gelfand

LE-218J

1195

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04/03/2008

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT

PAPER NUMBER

3774

MAIL DATE

DELIVERY MODE

04/03/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|---------------------------------------|--|
| Office Action Summary | Application No. 10/784,807 | Applicant(s) GELFAND ET AL. | |
| | Examiner William H. Matthews (Howie) | Art Unit 3774 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 and 64-66 is/are pending in the application.
- 4a) Of the above claim(s) 12-16, 19, 35-44, 53-57 and 60 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-34 is/are allowed.
- 6) ☒ Claim(s) 1-11, 17, 18, 20, 45-52, 58, 59 and 64-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2-27-08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed 2-27-08 have been fully considered but they are not persuasive.

Regarding Guiset, Applicant contend Guiset fails to increase renal pelvis pressure because Guiset disclose two states (apertures 3 are open, or apertures 3 are closed and aperture 4 is opened) in which renal pelvis pressure is not increased. Examiner disagrees. The renal pelvis is in fluid communication with bladder and ureters (applicant's published specification final sentence of paragraph 58). Therefore when either of apertures 3 or 4 are closed, the system is artificially closed and the kidneys are inherently producing and introducing fluid into the system thus increasing pressure therein.

Regarding Cionata et al., Applicant contend the urine drainage port prevents pressure from increasing within the renal pelvis or urinary tract. Examiner respectfully disagrees. Cionata et al. disclose the urinary drainage ports may be used to inject materials thus creating a positive pressure (c15:29-36). This step clearly inhibits a renal function although Examiner maintain the previous arguments that the anchoring balloon blocks the natural path of urine flow and thus inhibits a renal function as well.

Examiner notes Applicant has not argued the rejections under 35 U.S.C 103(a) regarding claims 4,48, and 62.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3,7-10,17,18,20,45-47,49-51,58,59,61,64,65 are rejected under 35 U.S.C. 102(b) as being anticipated by Guiset US PN 4044401.

3. Guiset et al. disclose in figure 1 and corresponding description a method of protecting a kidney or inhibiting a natural function of a kidney during surgery comprising artificially increasing pressure (by mere placement of balloon 27 or inflation by reservoir 23) which reduces or inhibits natural renal function and thereafter reducing pressure. Note the method disclosed may be utilized in a natural bladder rather than artificial rigid bladder 6.

4. Claims 1-3,5,6-11,17,18,20,45-47,49-52,58,59,61,64-66 are rejected under 35 U.S.C. 102(e) as being anticipated by Cioanta et al. US PN 6682555.

5. Cioanta et al. disclose a method of protecting a kidney or inhibiting a natural function of a kidney during surgery comprising artificially increasing pressure (by inflation of balloon 15 or 52, see figure 10B) which reduces or inhibits natural renal function and thereafter reducing pressure. Column 14, line 41 through column 15 line

28 disclose various contrast agents which may be delivered after pressure within the urinary tract is increased. Cionata et al. disclose the urinary drainage ports may be used to inject materials thus creating a positive pressure (column 15 lines 29-36).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 4,48,62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guiset US PN 4044401.

8. Guiset disclose the limitations of claims 4,48, and 62 as described above but lack the express written disclosure of increasing the pressure to about 15 cmH20.

However, Guiset disclose pressure created by pressing on reservoir 23 causing fluid 24 to inflate balloon 27 thereby increasing pressure inside the bladder in order to open the collar 16 and release urine. The pressure created must be sufficient to overcome a normally closed collar 16. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method disclosed by Guiset to provide a required pressure of at least about 15 cmH20 to open the collar in order to ensure the collar remain closed when urination is not required.

Allowable Subject Matter

9. Claims 21-34 are allowed.
10. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fail to disclose or substantially render obvious a method of preventing or treating contrast nephropathy in patients undergoing radiographic procedures comprising the steps of increasing pressure in a urinary tract, injecting contrast agent into a blood vessel, and reducing pressure in the urinary tract.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner
Art Unit 3774

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